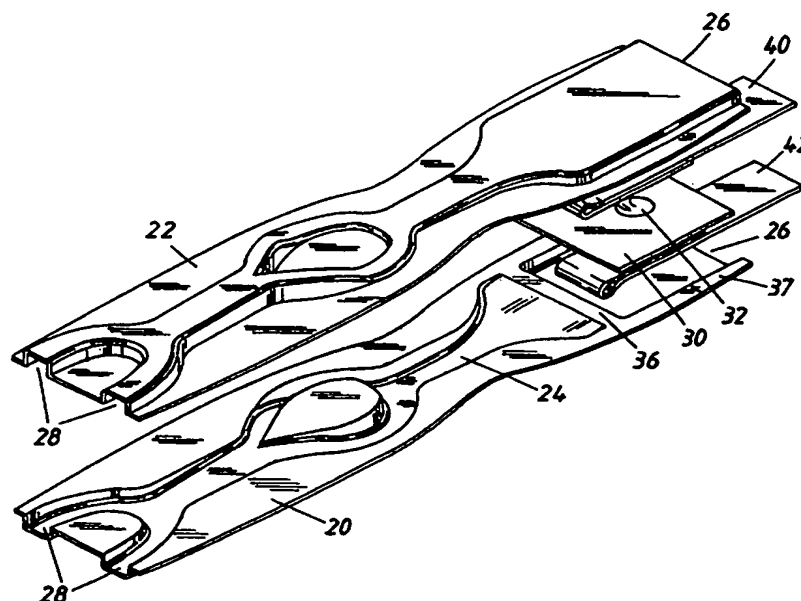




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(54) Title: SINGLE DOSE INHALER I



## (57) Abstract

A disposable inhaler including a deagglomeration section having a section inlet, a section outlet and a divider for splitting the stream of air into two flow parts either side of the divider, the divider having a surface facing the section inlet and orientated at an angle substantially perpendicular to the stream of air passing through the section inlet and the walls of the inhalation channel through the inhaler being shaped so as to cause substantially no resistance to or turbulence in the air flow through the inhaler.

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## SINGLE DOSE INHALER I

The present invention relates to a disposable inhaler, particularly for administering powder by inhalation.

5 Previously, as described in WO93/17728 and illustrated in Figures 1 to 3 of the accompanying drawings, there was known a disposable inhaler constructed from two parts 1 and 2. The lower part 2 includes a recesses 3 in which a dose of powder is stored and the two parts together define a channel through which a stream of air may be drawn by a user from an air inlet 4 to a mouthpiece 5. A tape 6 is provided to cover the recesses 3 and is  
10 additionally bent around the outside of the part 2 to cover an aperture 8 in the bottom of the recess 3. In use, the tape 6 is pulled away from the lower part 2 so as to expose both the aperture 8 and the recess 3. Projections 7 are provided to keep the loose tape out of the way of the air flow and a depression 9 directs the air flow to pick up the powder in the recess 3 more effectively. The channel defined by parts 1 and 2 also includes a deagglomeration  
15 section 10 having a section inlet 11, a section outlet 12 and a divider 13. The divider 13 splits the stream of air into two flow paths and powder is caused to impact on internal surfaces. In this way, powder is effectively deagglomerated.

In use, a patient inhales through the mouthpiece 5 causing an air stream to pick up the powder stored in recess 3. As the air/powder mixture flows through the inhaler, powder is  
20 deagglomerated then passes out of the mouthpiece 5 and into the lungs of the patient.

An object of the present invention is to provide improved deagglomeration of powder, in other words to increase the fine particle fraction and fine particle dose.

Another object of the present invention is to minimise retention of powder within the inhaler.

25 With regard to these two objects, the prior art of Figures 1 to 3 included an inhalation channel which directed the air flow along a path with walls that change direction. The changes in the direction of the walls results in powder impacting with those walls and a generally turbulent air flow which assists in deagglomeration of powder.

The present invention is based on the realization that the effects of deagglomeration of powder by the channelling surfaces or any of the surfaces facing downstream of the surfaces of the divider 13 are relatively insignificant.

According to the present invention there is provided an inhaler for administering  
5 powder by inhalation, the inhaler comprising:

a channel through which a stream of air may be drawn by inhalation of a user; and  
a powder dispenser for providing said powder in said stream of air for inhalation by  
the user; wherein

said channel includes at least one deagglomeration section with a section inlet, a  
10 section outlet downstream of said section inlet and a divider between said section inlet and  
said section outlet for dividing said stream of air either side of said divider; and wherein  
said divider has a surface opposite said section inlet and said surface is oriented at an  
angle substantially perpendicular to the flow of said stream of air passing through said  
section inlet.

15 In this way, powder carried in the air stream is more effectively deagglomerated and  
the final air/powder mixture inhaled by the user has a higher fine particle fraction and fine  
particle dose. By providing a perpendicular surface to the divider, there is greater impact of  
powder with the surface of the divider causing improved deagglomeration throughout the  
air/powder mixture. Furthermore, impact of the powder with the surface of the divider,  
20 together with the air flow past the surface prevents undue retention of powder on the  
surface. When a large powder particle impacts with the surface, it breaks into smaller  
particles which rebound back into the airflow and are carried on through the inhaler by that  
air flow.

Preferably, the surface of the divider extends over at least the area corresponding to a  
25 projection of the section inlet on to said divider.

By providing a perpendicular surface over the entire width of the section inlet, the  
effects and advantages discussed above are maximised.

According to the present invention there is also provided an inhaler for administering  
powder by inhalation, the inhaler comprising:

30 a channel through which a stream of air may be drawn by inhalation of a user; and

a powder dispenser for providing said powder in said stream of air for inhalation by the user; wherein

said channel includes at least one deagglomeration section with a section inlet, a section outlet downstream of said section inlet and a divider between said section inlet and said section outlet for dividing said stream of air either side of said divider, said divider having a surface substantially opposite said section inlet for dividing the air flow entering through said section inlet and affecting deagglomeration of powder in the air flow; and wherein

surfaces of the at least one deagglomeration section are shaped and spaced apart so as substantially not to cause any restriction to or turbulence in the stream of air through the inhaler.

According to the present invention, it has been recognised that most of the deagglomeration occurs on the surface of the divider opposite the section inlet and that, with the same size of inhaler and same fine particle fraction/dose, the shape of the walls defining the channel through the inhaler may be modified to reduce the flow resistance and retention of the inhaler.

In particular, with a particular shape and size of divider surface opposite the section inlet for deagglomeration of powder, the remaining surfaces of the deagglomeration section should be shaped to follow the natural flow path of the air deflected either side of the divider. Clearly, this results in reduced deagglomeration effects in the rest of the inhaler other than the deagglomeration surface. However, as mentioned above, the present invention recognises that the effects of deagglomeration in these parts are relatively insignificant. The advantages of the present invention are that, with reduced disturbance, restriction, turbulence etc of the stream of air, there is less opportunity for powder to be deposited in the inhaler and the flow resistance experienced by the user inhaling through the inhaler is minimised.

Each section inlet may be fed by one or more substantially straight sections or channels.

The advantage of this is that the powder particles carried in the stream of air then have a well defined momentum towards the facing surface of the deagglomeration divider. This

maximises the number of larger powder particles which leave the direction of flow of the stream of air and which continue straight on to impact with the divider.

Preferably, two deagglomeration sections are provided with the section outlet of one deagglomeration section being in fluid connection with the section inlet of the other  
5 deagglomeration section.

The channels formed either side of the divider of one deagglomeration section may feed directly into the section inlet of the next deagglomeration section or they may first join to form a single straight section feeding that section inlet.

The use of two deagglomeration sections provides further improvement in  
10 deagglomeration with further increases in the fine particle fraction and fine particle dose. In particular, the fine particles in the air/powder mixture will be carried by the airstream around the surface of the divider. However, those larger heavier particles which escaped deagglomeration by the first divider will have sufficient momentum to leave the flow of air and impact with the surface of the second divider. As with the first divider, the particles  
15 break into smaller particles which rebound back in to the airstream and are carried on through the inhaler. Of course, the exact shape and size of the second deagglomeration section may differ from that of the first deagglomeration section.

According to the present invention, there is also provided a method of optimizing the characteristics of an inhaler including a channel through which a stream of air may be  
20 drawn by inhalation of a user and a powder dispenser for providing said powder in said stream of air for inhalation by the user, said channel including at least one deagglomeration section with a section inlet, a section outlet downstream of said section inlet and a divider between said section inlet and said section outlet for dividing said stream of air either side of said divider, the method comprising:

25 providing a surface for deagglomeration of the powder on the divider opposite said section inlet and extending over an area corresponding to a projection of the section inlet onto said divider; and

choosing dimensions for the rest of the deagglomeration section which cause substantially no restriction to or turbulence in the stream of air through the inhaler.

According to the present invention, there is also provided a method of optimizing the characteristics of an inhaler including a channel through which a stream of air may be drawn by inhalation of a user and a powder dispenser for providing said powder in said stream of air for inhalation by the user, the method comprising:

5       shaping and sizing the channel so as to cause substantially no restriction to or turbulence in the stream of air in the channel; and

causing the channel to change direction with a sufficient angle such that the momentum of particles of powder in the air stream requiring deagglomeration will cause the particles to leave the air flow and impact walls of the channel.

10       According to the present invention, there is also provided a method of providing deagglomerated powder at the outlet of a channel guiding a stream of air, the channel including at least one deagglomeration section with a section inlet, a section outlet downstream of said section inlet and a divider between said section inlet and said section outlet for dividing said stream of air either side of said divider, the method comprising:

15       providing powder in said channel upstream of said section inlet; and

providing a surface on said divider which is opposite said section inlet and which is orientated at an angle substantially perpendicular to the flow of the stream of air passing through said section inlet.

20       According to the present invention, there is also provided a method of providing deagglomerated powder at the outlet of a channel guiding a stream of air, the channel including at least one deagglomeration section with a section inlet, a section outlet downstream of said section inlet and a divider between said section inlet and said section outlet for dividing said stream of either side of said divider, said divider having a surface substantially opposite said section inlet for dividing the air flow entering through said  
25       section inlet and affecting deagglomeration of powder in the air flow, the method comprising:

providing powder in the channel upstream of said section inlet; and

shaping and spacing the surfaces of the channel so as substantially not to cause any restriction to or turbulence in the stream of air through the inhaler.

Medicaments suitable for administration by using the present invention are any which may be delivered by inhalation. Suitable inhalable medicaments may include for example  $\beta$ 2-adrenoreceptor agonists for example salbutamol, terbutaline, rimeterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, TA-2005, mabuterol and the like, and their pharmacologically acceptable esters and salts; anticholinergic bronchodilators for example ipratropium bromide and the like; glucocorticosteroids for example beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone, and the like, and their pharmacologically acceptable esters and salts; anti-allergic medicaments for example sodium cromoglycate and nedocromil sodium; expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists, phospholipase-A2 (PLA2) inhibitors, platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments, tranquilisers, cardiac glycosides, hormones, antihypertensive medicaments, antidiabetic- antiparasitic- and anticancer- medicaments, sedatives and analgesic medicaments, antibiotics, antirheumatic medicaments, immunotherapies, antifungal and antihypotension medicaments, vaccines, antiviral medicaments, proteins, polypeptides and peptides for example peptide hormones and growth factors, polypeptides vaccines, enzymes, endorphines, lipoproteins and polypeptides involved in the blood coagulation cascade, vitamins and others, for example cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

The present invention will be more clearly understood from the following description, given by way of example only, with reference to the accompanying drawings in which:

- Figure 1 illustrates a previous inhaler;
- Figure 2 illustrates the previous inhaler of Figure 1 separated into two parts;
- Figures 3a, 3b and 3c illustrate a cross-section of the inhaler of Figure 1;
- Figure 4 illustrates the air flow path through one half of an inhaler;
- Figure 5 illustrates an inhaler according to the present invention;
- Figure 6 illustrates the inhaler of Figure 5 separated into its component parts;



Figure 7 illustrates the main two parts of Figure 5 from below;

Figure 8 illustrates a cross-section of the inlet of the inhaler of Figure 5;

Figure 9 illustrates the shape of the channel section through the inhaler of Figure 5;

Figures 10(a) to (d) illustrate the dimensions of the channel section of Figure 9;

5 Figure 11 illustrates the flow path through half of the channel section of Figure 9;

Figure 12 illustrates the channel section of an alternative inhaler;

Figure 13 illustrates schematically a side view of the inhaler of Figure 6; and

Figure 14 illustrates an inhaler according to the present invention.

As illustrated in Figures 5, 6 and 7, the inhaler is constructed from a first part 20 and a  
10 second part 22 which together define an inhalation channel 24 joining an air inlet 26 and an  
outlet 28. In this illustrated embodiment, the outer shape of the inhaler corresponds to the  
inner channelled shape. Clearly, however, this is not necessary and the outer shape may  
take any other form.

At an inlet end of the inhaler, a plate 30 is provided. The plate 30 has a depression 32  
15 in which a dose of powder is stored. The use of a separate plate 30 in which the depression  
32 is formed is particularly advantageous, since it allows the depression 32 to be made  
from a material different from that of the two parts 20 and 22. In particular, it is  
advantageous to make the depression 32 from a strong water impermeable material such as  
aluminium or aluminium laminate, whereas the first and second parts 20 and 22 may be  
20 constructed of transparent plastics material, such that the inhalation channel maybe  
inspected before and after use.

As illustrated in Figure 8, the plate 30 is secured to the first part 20 by means of a  
support 36. Preferably, the plate 30 is also secured to the first part 20 along its edges 37 so  
as to form an enclosed cavity 38 underneath the depression 32.

25 As illustrated in the Figures, two tapes 40,42 are provided respectively for sealing the  
upper open portion of depression 32 and an aperture 44 provided in the bottom of the  
depression 32. Preferably, as illustrated, the free ends of the two tapes 40 and 42 are joined  
together.

In use, the two tapes 40 and 42 are simultaneously pulled out of the air inlet 26 so as to  
30 be peeled back from the depression 32, thereby exposing the open upper surface of

depression 32 and the aperture 44 in the bottom of depression 32. When the user inhales through the outlet 28 of the inhaler, air is drawn into the air inlet 26, picking up powder 34 from the depression 32. Furthermore, a pressure difference is created between the channel above the plate 30 and the cavity 38 formed below the plate 30. In this way, air is drawn in the lower part of the air inlet 26 and through the aperture 44 in the bottom of the depression 32. This assists in ensuring that the powder contained in the depression 32 is transferred into the stream of air flowing through the inhaler.

By providing the depression 32 in a plate 30 housed within the inhaler as described above, the depression 32 is protected from being damaged and there is less chance of the depression 32 being accidentally opened, particularly by removal of the tape covering the aperture 44 in the bottom of depression 32. Furthermore, this arrangement allows additional air to be drawn into the system through the aperture 44 in the bottom of the depression 32 whilst ensuring that all air entering the system enters via the air inlet 26. In this way, there is less likelihood of the user accidentally blocking the aperture 44.

Figure 4 illustrates the streamlines which occur in one half of an inhaler where the angles of the walls of the inhalation channel have been optimized and a second divider has been introduced. Even though this inhaler gives excellent results, it is now realised that the impact of the airstream with walls of the channel downstream of the dividers gives little significant improvement in deagglomeration of powder.

Figure 9 illustrates a preferred shape of the walls of the channel resulting from the present invention and Figure 11 illustrates the resulting streamlines.

Firstly, a general explanation of the flow of the air and powder will be given with reference to Figure 9.

As explained before, air enters through the air inlet 26 and picks up powder 34 from the depression 32. The air powder mixture is then channelled by walls 50 into a first acceleration section 52. In the acceleration section 52, powder in the air/powder mixture, particularly the larger particles of powder, are brought into a stable axial flow before entering the first deagglomeration section 54. Opposite the section inlet 56 of the first deagglomeration section 54, a deagglomeration surface 58 of the first divider 60 is orientated perpendicular to the flow of the air/powder mixture as it passes through the

section inlet 56. Preferably, and as illustrated, the deagglomeration surface 58 is generally planar, extends to the width of the section inlet 56 and is in alignment with the section inlet 56.

As illustrated in Figure 11, the stream of air flows either side of the divider 60 with a smooth curved flow path. However, the particles of powder in the air stream, particularly the heavier particles of powder have sufficient axial momentum that they continue in a substantially straight line so as to impact with the deagglomeration surface 58. Upon impact, the particles break up into smaller constituent particles and rebound back into the air stream where they continue to flow with the air around the two side channels 62 and 64 of the first deagglomeration means 54.

At the section outlet 66 of the first deagglomeration section 54, the airflows of the two side channels 62 and 64 are recombined and enter into the second acceleration section 68.

In the second acceleration section 68, just as with the first acceleration section 52, the powder particles are once again brought into a stable flow with a strong axial momentum. At the section inlet 70 of the second deagglomeration section 72, once again the air flows smoothly either side of the second divider 74 along the two side channels 76 and 78. However, particles with sufficient axial momentum will leave the airstream and impact upon the deagglomeration surface 80 of the second divider 74. Just as with the deagglomeration surface 58 of the first divider 60, particles which impact the deagglomeration surface 80 will be broken down into smaller particles and rebound into the airstream to be carried down the side channels 76 and 78.

It will be appreciated that in the case of both the first and second deagglomeration sections, powder of sufficiently small size will be carried by the air flow around the respective divider 60, 74 without impacting upon the deagglomeration surface 58, 80. It will only be the larger particles which require deagglomeration that will have sufficient momentum to leave the airstream and impact with the deagglomeration surfaces 58 and 80. Thus, it will be appreciated that the acceleration section 68 will contain a higher proportion of fine particles than the accelerations section 52 and, therefore, a larger number of powder particles will be deflected around the second divider 74 without impacting its deagglomeration surface 80 than will be deflected around the divider 60 without impacting

its deagglomeration surface 58. It will also be appreciated that the second deagglomeration section 72 acts to deagglomerate large particles which escaped deagglomeration by the first deagglomeration section 54. Particles which were deagglomerated by the first deagglomeration section 54 should merely flow around the second divider 74 without  
5 impacting upon its deagglomeration surface 80.

It is possible to provide third or subsequent deagglomeration sections similar to that of the first deagglomeration section 54. However, this results in an increase of the overall size of the inhaler, together with increased flow resistance through the inhaler for little improvement in deagglomeration.

10 As illustrated in Figure 9, the second deagglomeration section 72 preferably comprises a section outlet made up of respective outlets from the side channels 76 and 78. By providing an outlet in this way, the size of the inhaler may be reduced with no adverse effect to its characteristics. Preferably, the section outlet 82 and, therefore, the inhaler outlet 28 is formed at a position where the air/powder mixture flow in the side channels 76  
15 and 78 is substantially axial. This provides the best flow into the mouth of the user.

The preferred shape and size of the inhaler of Figure 9 is best described with reference to Figures 10(a), (b), (c) and (d). These Figures illustrate the various parts of Figure 9, but, rather than being annotated with reference numerals, are annotated with the preferred dimensions given in millimetres and, in one case, degrees. Where a number is prefixed by  
20 the letter R, the number refers to the radius of curvature of the indicated portion given in millimetres.

For the avoidance of doubt, Figure 10(a) illustrates all of the channel illustrated in Figure 9, Figure 10(b) illustrates the lower channel wall of the inhaler as illustrated in Figure 9 where the upper wall has identical dimensions, but symmetrically reversed, Figure  
25 (c) illustrates the first divider 60 of the inhalation channel of Figure 9 and Figure 10(d) illustrates the second divider 74 of the inhalation channel of Figure 9.

The inhalation channel defined by Figures 10(a) to (d) produces the streamlines illustrated in Figure 11. As illustrated, there is virtually no disruption to the flow of air through the inhaler, such that, apart from powder being caused to impact with the  
30 deagglomeration surfaces of the dividers 60 and 74, powder will be smoothly carried

through the inhaler such that deposition and retention of powder is minimized. Similarly, with a smooth disturbance free flow, the flow resistance is minimised, thereby making inhalation easier for the user and maximising the transfer of his or her effort in inhalation into lifting, carrying and deagglomerating powder in the inhaler.

5 It will be appreciated that many of the dimensions illustrated in Figures 10(a) to (d) may be changed without departing from the present invention. Nevertheless, many of the dimensions are strongly interrelated such that changing one dimension may require many other dimensions to be changed similarly to achieve the effects described above and illustrated in Figure 11. Figure 12 illustrates an alternative embodiment where the side  
10 channels 84 of the first divider 86 themselves form an acceleration section. As illustrated, the two side channels 84 recombine at the second section inlet 87 so that there are two air flows at the section inlet 87 inclined relative to one another at a small angle. Nevertheless, the deagglomeration surface 88 of the second divider 89 is still substantially perpendicular to these two flows, since the angle between the two flows is relatively small. In the  
15 illustrated embodiment, the two flows enter the second deagglomeration section through a section inlet 87 with a single opening. However, it is also possible to provide two closely spaced separate openings, though this might make construction more difficult and, in some cases, promote retention downstream of the adjoining wall. In either case, the two air flows form a single air flow which projects powder towards the perpendicular deagglomeration  
20 surface 88.

The construction of an inhaler channel such as illustrated in Figures 9 and 10 or in Figure 12 is dictated by many conflicting factors. For example, by introducing further deagglomeration sections, deagglomeration may be improved, but the size of the inhaler is increased, flow resistance is increased and retention is also likely to be increased. By  
25 increasing the cross-sectional area of the channel, the flow resistance can be reduced, but the flow velocity will also be reduced, such that it is difficult to achieve sufficient deagglomeration. Furthermore, the overall size of the inhaler is increased. By decreasing the cross-sectional area of the inhaler, the size of the inhaler would be reduced and the flow velocity would be increased, thereby potentially assisting in deagglomeration. However,  
30 flow resistance would be increased and there comes a point where, in small channels, it

becomes extremely difficult to achieve a smooth undisturbed flow as illustrated in Figure 11.

It is also possible to vary individual features of the inhaler. For instance, by shortening the lengths of the acceleration sections 52, 68 and 84, the inhaler size can be reduced, but at some point, the acceleration sections 52, 68 and 84 will become less effective in imparting the correct momentum to the carried particles. Similarly, the width of the acceleration sections 52 and 68 could be increased relative to the dividers 60 and 74, but, at some point, powder particles at the edges of the acceleration sections 52 and 68 will pass around the dividers 60 and 74 without impacting upon them. In contrast, if the dividers 60 and 74 are increased in width to correspond to the width of the acceleration sections 52 and 68, there will come a point when flow around the deagglomeration surfaces 58 and 80 of the dividers 60 and 74 will create an unacceptably large dead space from which powder particles will not rebound and retention will occur.

Thus, from the above, it will be appreciated that the present invention can be applied and can give rise to great advantages with a whole range of shapes of inhalation channel, the actual shape being determined by the start parameters for that channel. It will also be appreciated that, from the selection described above, the particular choice of parameters by which to optimise the inhalation channel and the inhaler as a whole would not be obvious.

As illustrated, the acceleration sections preferably have a cross-sectional area of the order of  $16\text{mm}^2$  and, again as illustrated, are preferably formed as an approximate square. It is believed that the cross-sectional area could be increased to approximately  $30\text{mm}^2$  before the inhaler became too large and particle speed too low and could be reduced to a cross-sectional area of approximately  $9\text{mm}^2$  before the flow resistance became too great and the flow patterns too difficult to control. To optimise the deagglomeration of powder, the surface of each divider 60 and 74 facing its corresponding section inlet 56 and 70 should be substantially perpendicular to the air flow in the acceleration sections 52 and 60 across the entire width of the section inlets 56 and 70. This ensures that any large particle being carried in the flow in the acceleration sections 52 and 68 and which continues to travel generally in a axial direction will hit a divider 60, 74 in a generally perpendicular direction. This provides the maximum amount of energy to break up the particle. The rest of the

shape of the side channels 62, 64, 76, 78 and the dividers 60 and 74 can then be determined to minimise the disruption and turbulence caused to the flow of air and powder.

Figure 13 illustrates schematically a side view of an inhaler such as described with reference to Figures 5 to 12. As is clear from Figure 13, the inhaler extends in a generally first direction between the air inlet 26 and the outlet 28. Furthermore, the inhaler is of a  
5 generally flat construction, such that it extends in an elongate manner in a direction perpendicular to the first direction or, in other words, has a shallow extended rectangular or oval shape.

As illustrated in Figure 13, unlike previous inhalers of this general form, the inhaler is  
10 not completely flat along its length, but, at position 90, is deflected downwards, such that it is displaced in a third direction perpendicular to both the first and second directions. This deflection or displacement provides a downwardly extended wall 92, which, in use, may be pressed against the lower lip of the user. In this way, the user can assuredly insert the inhaler into his or her mouth by the correct amount. Indeed, because of the shape of the  
15 inhaler, it will feel strange to insert the inhaler by less than the correct amount. In this way, the inhaler will be inserted with the outlet 28 over and clear of the user's tongue, rather than in a position where the user's tongue could still impede the flow of air/powder from the outlet into his or her lungs.

It is desirable that the inhaler retains its generally flat form. Therefore, at position 94,  
20 the inhaler is deflected back upwardly such that it is displaced or bent in a direction opposite to the third direction. In this way, the inhaler may have the required function and yet retain a pleasing gentle S-bend form.

In the preferred embodiment illustrated in Figure 13, at position 90, the lower section  
25 has a radius of curvature of approximately 5mm and the upper section a radius of curvature of approximately 8mm and at the second position 94, the lower section has a radius of curvature of approximately 8mm and the upper section a radius of curvature of approximately 5mm.

Preferably, the downward bend occurs at approximately 30mm from the outlet 28.

As also illustrated in Figure 13, a plane 96 exists which passes within the inhaler. Shaping the inhaler with such a plane is highly advantageous, since, as illustrated, the inhaler can be more easily formed from only two moulded parts which are subsequently joined together along a flat surface.

5        This construction is particularly advantageous, since it does not require the use of a separate or special mouthpiece or any special indication on the inhaler. The inhaler comprises the same number of parts as an entirely flat inhaler, with no significant modification. Nevertheless, it provides a clear indication to the user as to how far it should be inserted into his or her mouth.

10       Figure 14 illustrates an inhaler which could embody the various aspects of the present invention. It will be appreciated that the outer shape of the inhaler has no direct relevance on the present invention, though of course the design of an inhalation channel meeting the requirements of the present invention might necessarily put certain constraints on that outer shape.



CLAIMS

1. An inhaler for administering powder by inhalation, the inhaler comprising:  
a channel through which a stream of air may be drawn by inhalation of a user; and  
5 a powder dispenser for providing said powder in said stream of air for inhalation by  
the user; wherein  
said channel includes at least one deagglomeration section with a section inlet, a  
section outlet downstream of said section inlet and a divider between said section inlet and  
said section outlet for dividing said stream of air either side of said divider; and wherein  
10 said divider has a surface opposite said section inlet and said surface is oriented at an  
angle substantially perpendicular to the flow of said stream of air passing through said  
section inlet.
2. An inhaler according to claim 1 wherein the surface of the divider extends over at  
15 least an area corresponding to a projection of the section inlet onto said divider.
3. An inhaler according to claim 1 or 2 wherein a central section of said surface is  
planar.
- 20 4. An inhaler according to claim 3 wherein said planar section extends over  
substantially all of the area corresponding to a projection of the section inlet onto said  
divider.
5. An inhaler according to any preceding claim wherein surfaces of the at least one  
25 deagglomeration section are shaped and spaced apart so as substantially not to cause any  
restriction to or turbulence in the stream of air through the inhaler.

6. An inhaler for administering powder by inhalation, the inhaler comprising:  
a channel through which a stream of air may be drawn by inhalation of a user; and  
a powder dispenser for providing said powder in said stream of air for inhalation by  
the user; wherein
- 5        said channel includes at least one deagglomeration section with a section inlet, a  
section outlet downstream of said section inlet and a divider between said section inlet and  
said section outlet for dividing said stream of air either side of said divider, said divider  
having a surface substantially opposite said section inlet for dividing the air flow entering  
through said section inlet and affecting deagglomeration of powder in the air flow; and
- 10        wherein
- surfaces of the at least one deagglomeration section are shaped and spaced apart so  
as substantially not to cause any restriction to or turbulence in the stream of air through the  
inhaler.
- 15        7. An inhaler according to any preceding claim wherein said channel includes a  
substantially straight section joined to said section inlet.
8. An inhaler according to any preceding claim wherein two deagglomeration sections  
are provided, the section outlet of one deagglomeration section being in fluid connection
- 20        with the section inlet of the other deagglomeration section.
9. An inhaler according to any preceding claim having an outlet from which air and  
powder may be inhaled, the outlet comprising the section outlet of said at least one  
deagglomeration section and the section outlet comprising two openings, one either side of
- 25        said divider.
10. An inhaler according to claim 9 wherein said two openings are positioned relative to  
said divider such that the air flow through said two openings are parallel.

11. A method of optimizing the characteristics of an inhaler including a channel through which a stream of air may be drawn by inhalation of a user and a powder dispenser for providing said powder in said stream of air for inhalation by the user, said channel including at least one deagglomeration section with a section inlet, a section outlet  
5 downstream of said section inlet and a divider between said section inlet and said section outlet for dividing said stream of air either side of said divider, the method comprising:

providing a surface for deagglomeration of the powder on the divider opposite said section inlet and extending over an area corresponding to a projection of the section inlet onto said divider; and

10 choosing dimensions for the rest of the deagglomeration section which cause substantially no restriction to or turbulence in the stream of air through the inhaler.

12. A method of optimizing the characteristics of an inhaler including a channel through which a stream of air may be drawn by inhalation of a user and a powder dispenser for  
15 providing said powder in said stream of air for inhalation by the user, the method comprising:

shaping and sizing the channel so as to cause substantially no restriction to or turbulence in the stream of air in the channel; and

causing the channel to change direction with a sufficient angle such that the  
20 momentum of particles of powder in the air stream requiring deagglomeration will cause the particles to leave the air flow and impact walls of the channel.

13. A method of providing deagglomerated powder at the outlet of a channel guiding a stream of air, the channel including at least one deagglomeration section with a section  
25 inlet, a section outlet downstream of said section inlet and a divider between said section inlet and said section outlet for dividing said stream of air either side of said divider, the method comprising:

providing powder in said channel upstream of said section inlet; and

providing a surface on said divider which is opposite said section inlet and which is orientated at an angle substantially perpendicular to the flow of the stream of air passing through said section inlet.

- 5 14. A method of providing deagglomerated powder at the outlet of a channel guiding a stream of air, the channel including at least one deagglomeration section with a section inlet, a section outlet downstream of said section inlet and a divider between said section inlet and said section outlet for dividing said stream of either side of said divider, said divider having a surface substantially opposite said section inlet for dividing the air flow  
10 entering through said section inlet and affecting deagglomeration of powder in the air flow, the method comprising:

providing powder in the channel upstream of said section inlet; and

shaping and spacing the surfaces of the channel so as substantially not to cause any restriction to or turbulence in the stream of air through the inhaler.

15

15. Use of an inhaler as described in any of claims 1 to 10 wherein said powder contains a pharmaceutically active substance.

16. Use according to claim 15 wherein the said substance is systemically active.

20

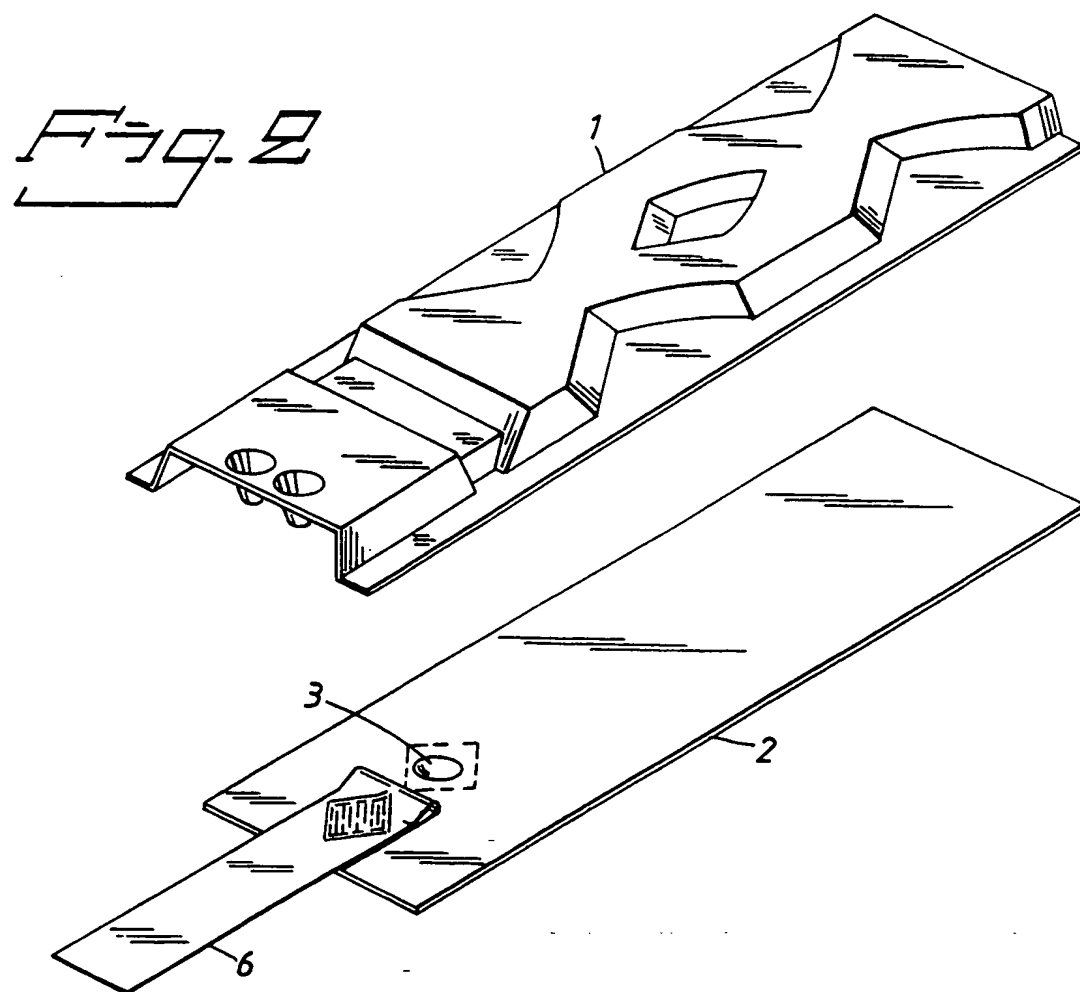
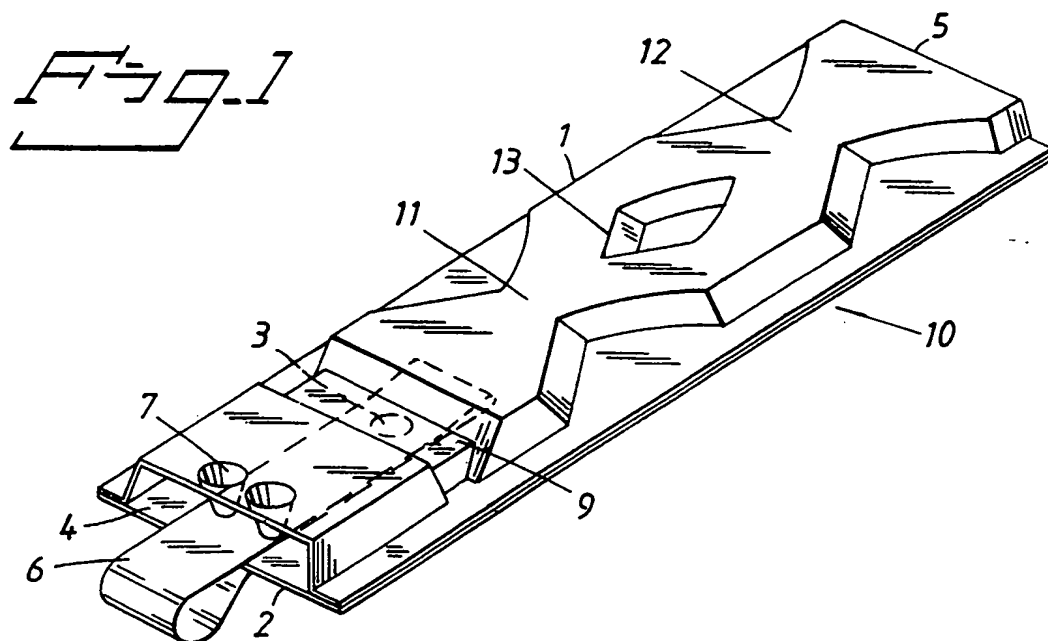
17. Use according to claim 15 wherein said substance is active in the bronchial area.

18. Use according to claim 17 wherein said substance is used in treatment of a bronchial disease.

25

19. Use according to claim 18 wherein said substance is used in the treatment of asthma.

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Fig. 3a

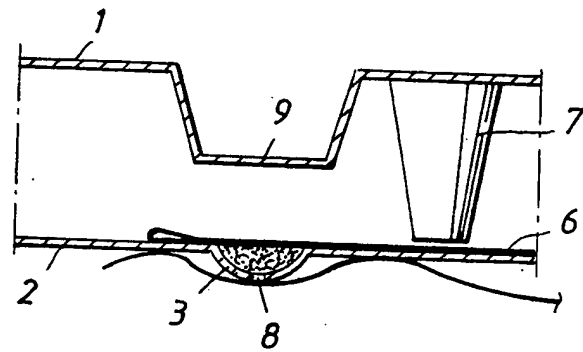


Fig. 3b

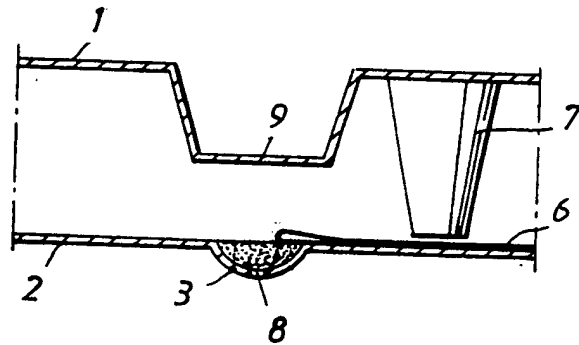
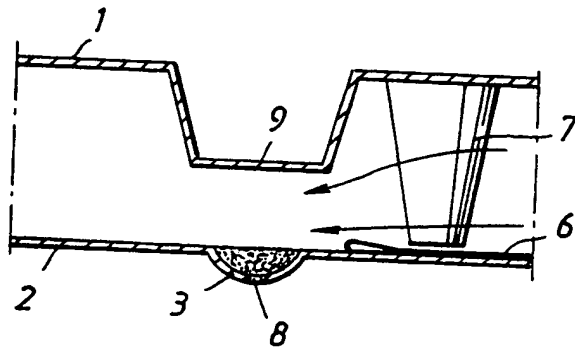


Fig. 3c

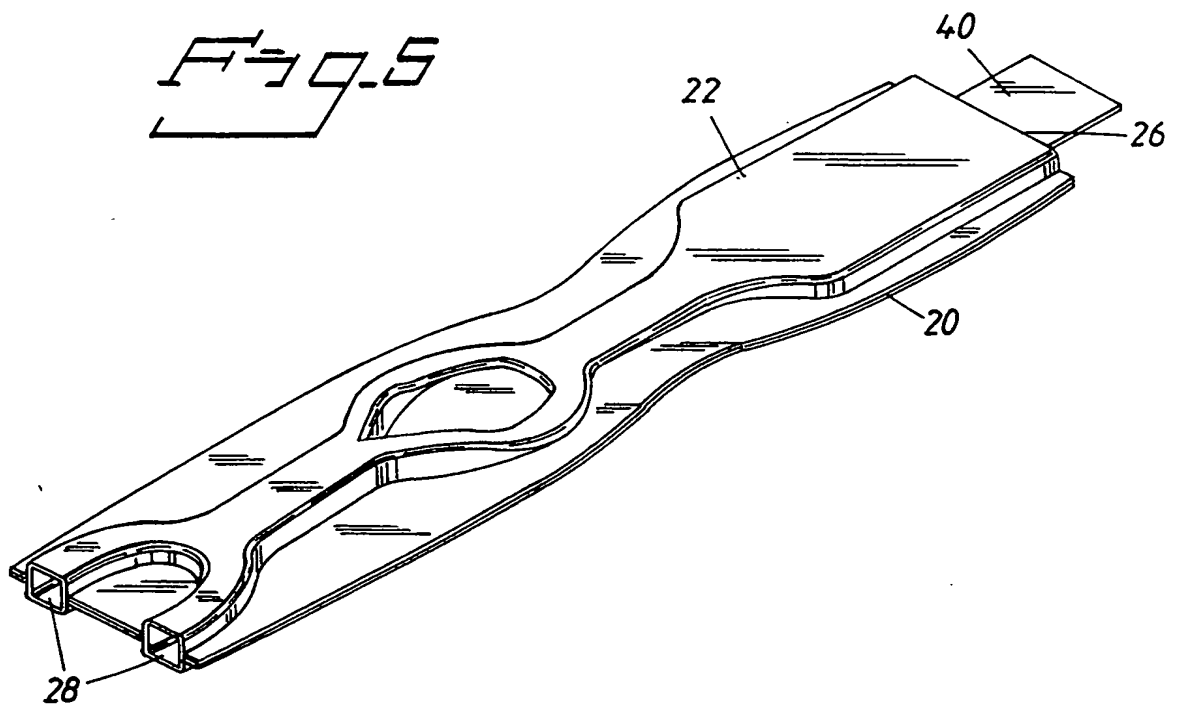


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Fig. 4



Fig. 5



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Fig. 6

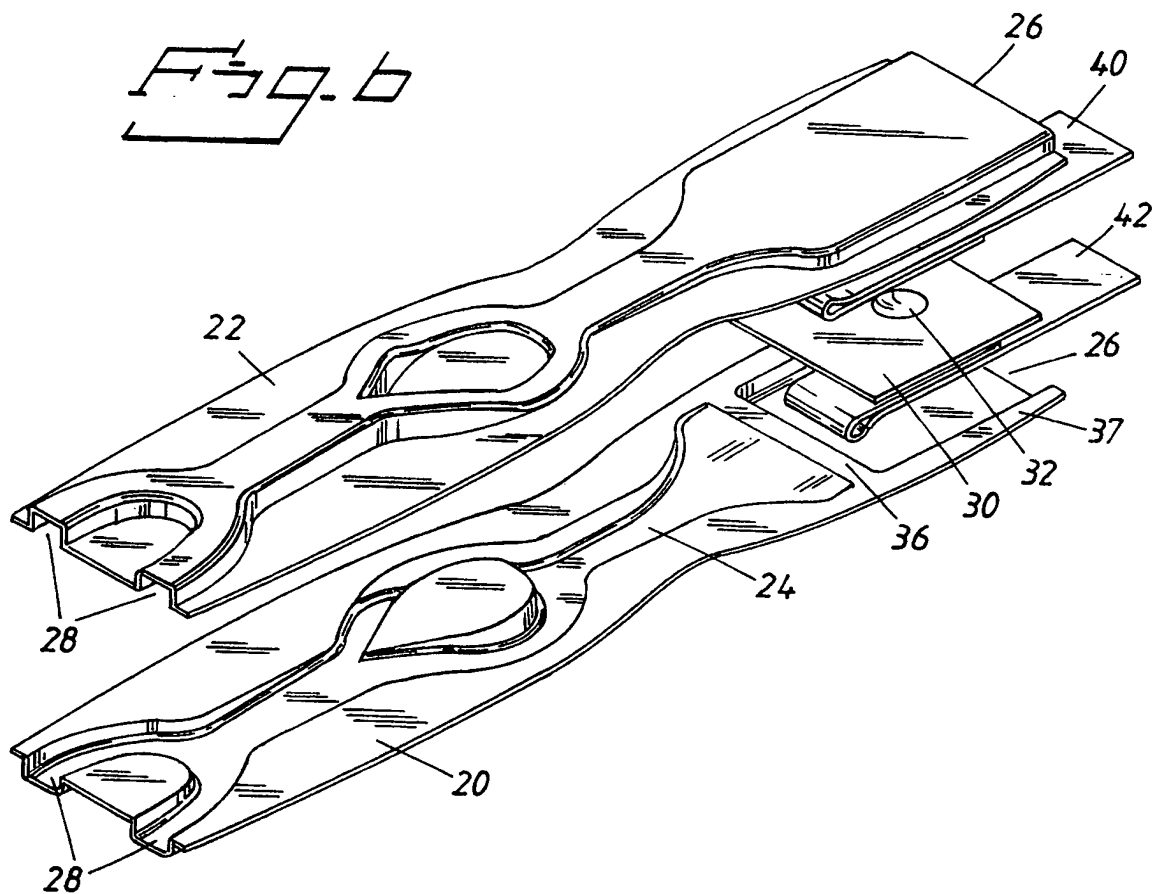
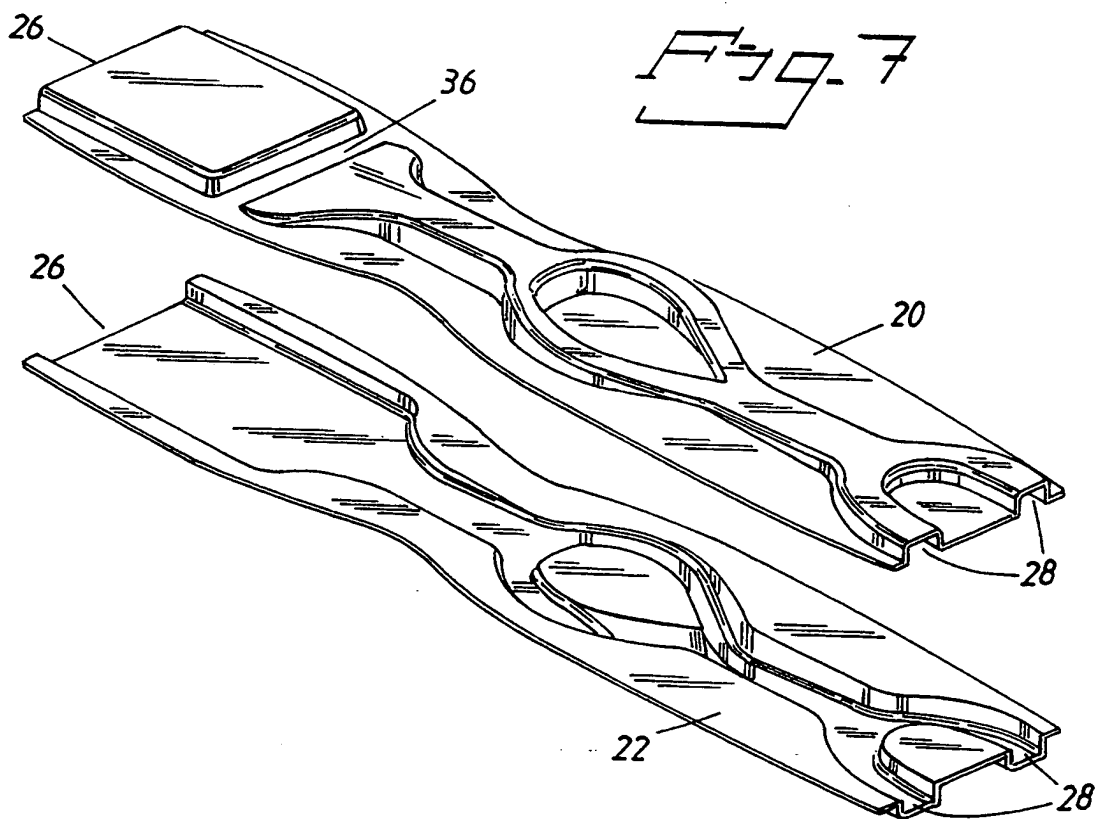


Fig. 7





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Fig. 8

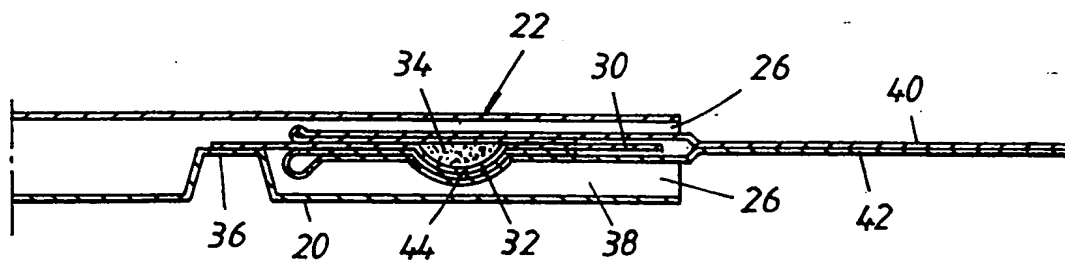


Fig. 9

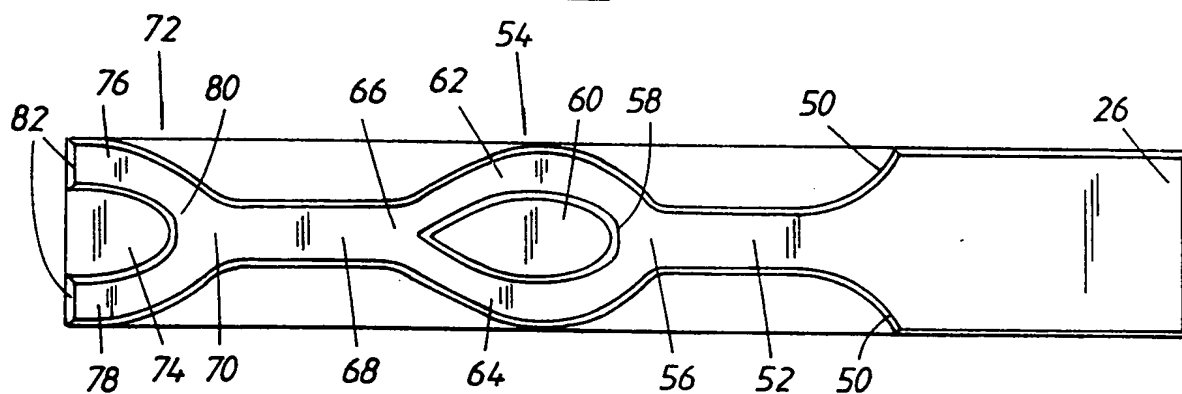
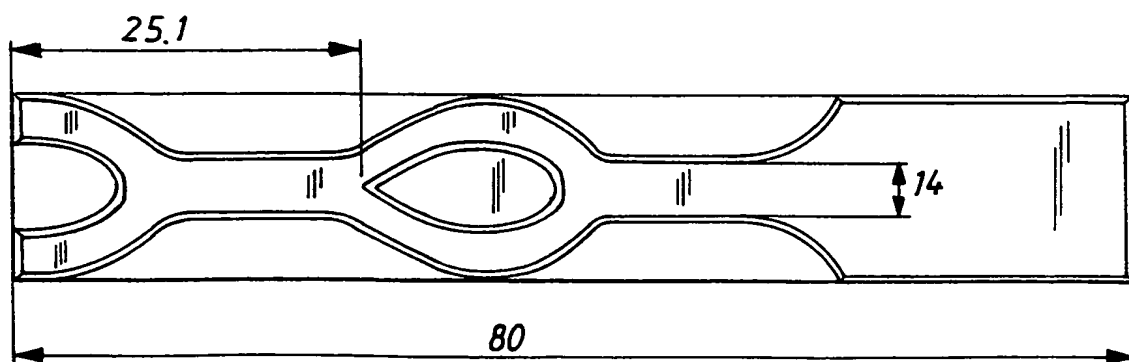


Fig. 10a



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Fig. 10d

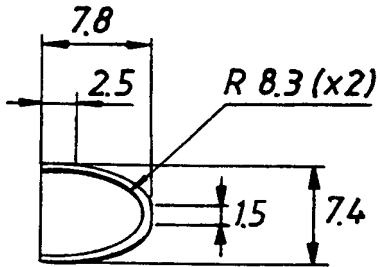


Fig. 10c

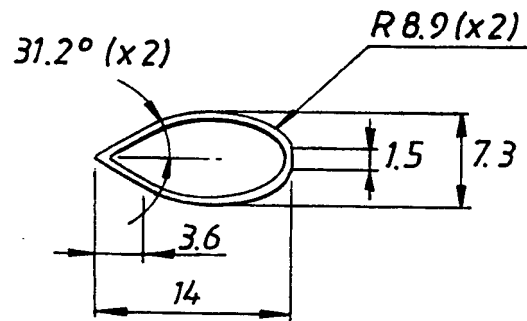


Fig. 10b

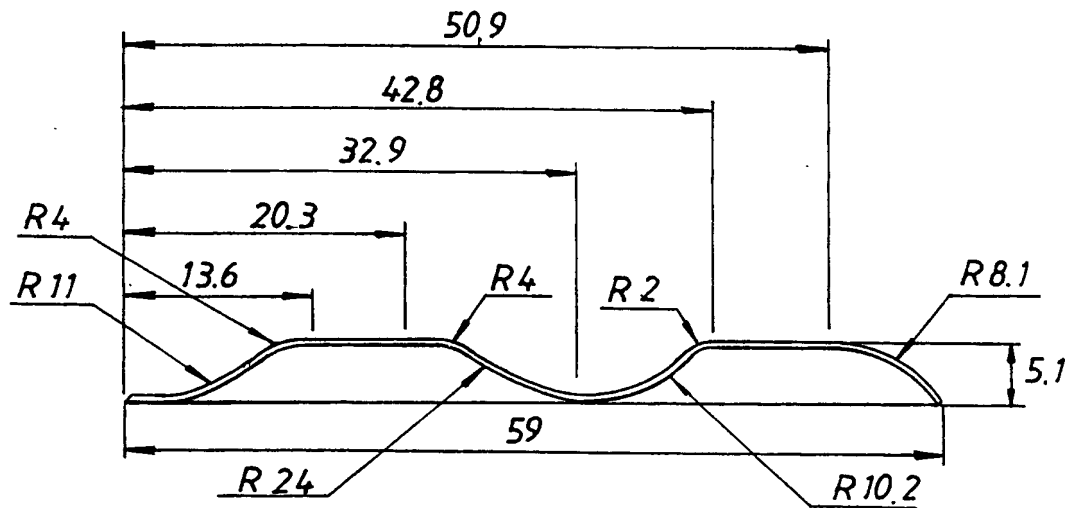


Fig. 11



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Fig. 12

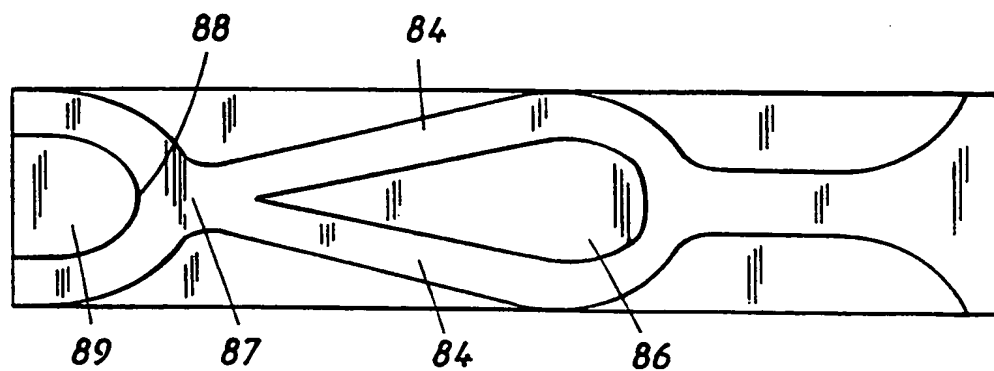


Fig. 13

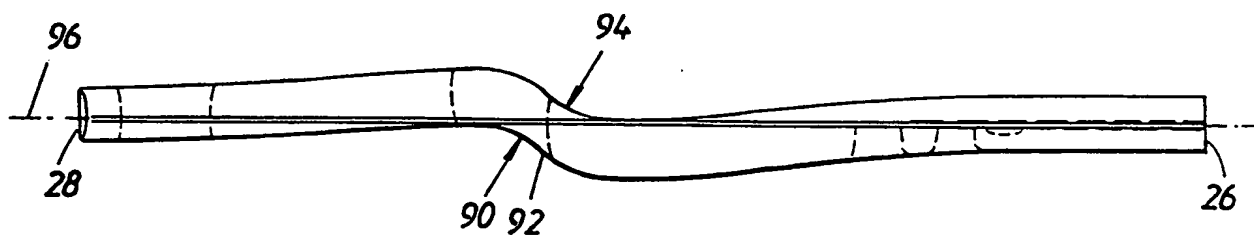
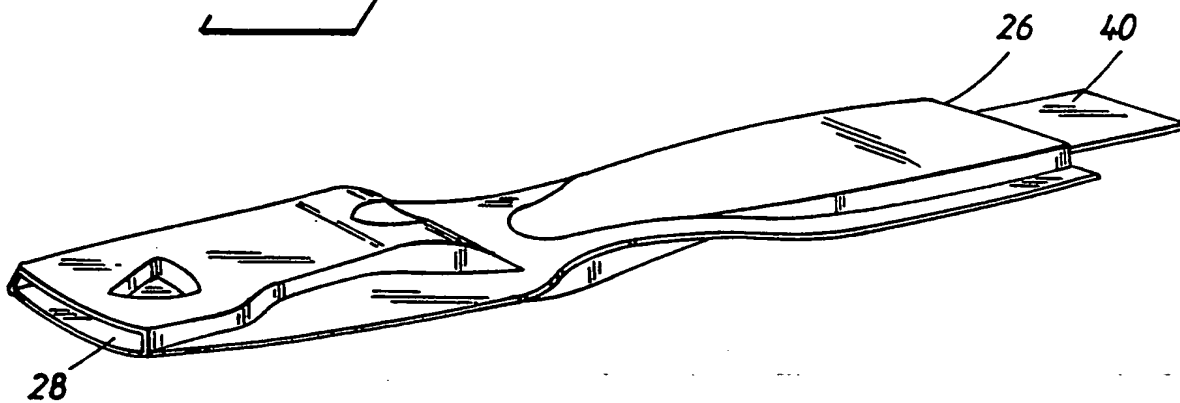


Fig. 14



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 98/00129

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 15/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 9705918 A1 (ASTRA AKTIEBOLAG), 20 February 1997 (20.02.97), page 7, line 1 - page 9, line 29, figure 4  --	1-17
A	WO 9317728 A1 (AKTIEBOLAGET ASTRA), 16 Sept 1993 (16.09.93), page 4, line 25 - page 5, line 25, figure 1  --	1-17
A	US 5437271 A (PETER D. HODSON ET AL), 1 August 1995 (01.08.95), column 4, line 65 - column 5, line 25, figure 4  -- -----	1-17

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

18 May 1998

Date of mailing of the international search report

25 -05- 1998

Name and mailing address of the ISA/

Swedish Patent Office

Box 5055, S-102 42 STOCKHOLM

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Authorized officer

Eva Selin

Telephone No. +46 8 782 25 00

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE98/00129

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 18-19  
because they relate to subject matter not required to be searched by this Authority, namely:  
A method for treatment of the human or animal body by therapy  
(Article 17 (2) (a) (i) and Rule 39.1(iv)).
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐

The additional search fees were accompanied by the applicant's protest.

☐

No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

29/04/98

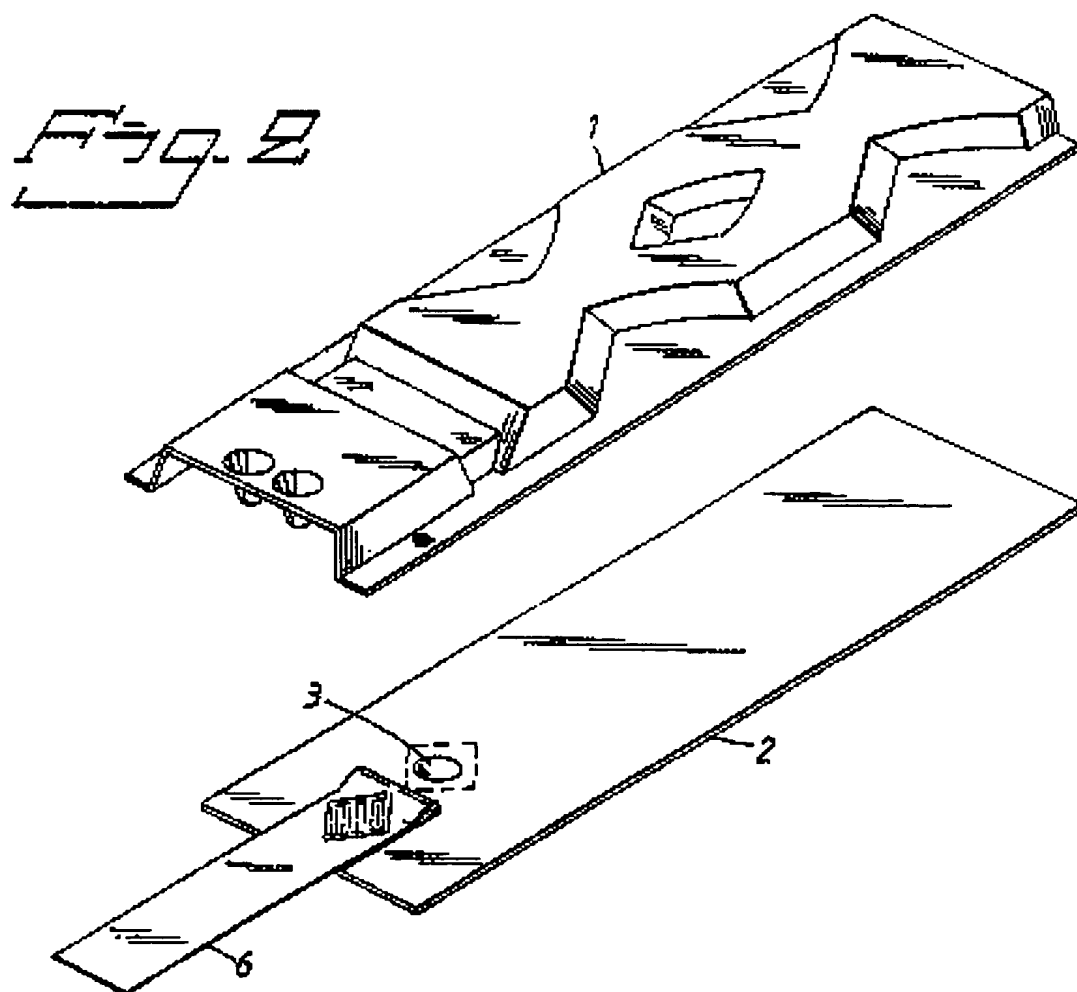
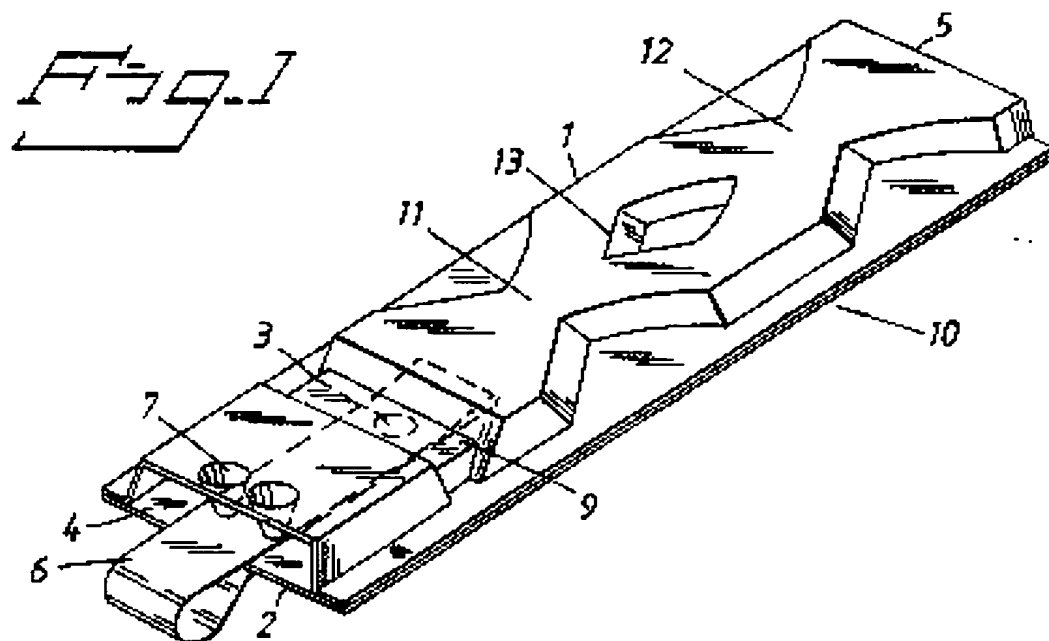
International application No.  
PCT/SE 98/00129

23/04/98

FCI/SE 98/00129

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9705918 A1	20/02/97	AU 6539296 A NO 980484 D SE 9502800 D	05/03/97 00/00/00 00/00/00
WO 9317728 A1	16/09/93	AU 666171 B CA 2131157 A CN 1032293 B CN 1080875 A CZ 281883 B CZ 9402084 A EP 0558879 A,B EP 0629136 A FI 944034 A HU 69090 A HU 9402541 D JP 7508184 T NO 943211 A NZ 249128 A SK 104994 A US 5533505 A ZA 9301520 A	01/02/96 16/09/93 17/07/96 19/01/94 12/03/97 18/01/95 08/09/93 21/12/94 02/09/94 28/08/95 00/00/00 14/09/95 30/08/94 26/01/96 12/04/95 09/07/96 06/09/93
US 5437271 A	01/08/95	NONE	

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Fig. 3a

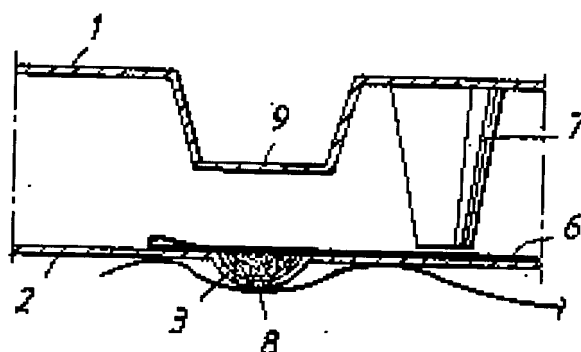


Fig. 3b

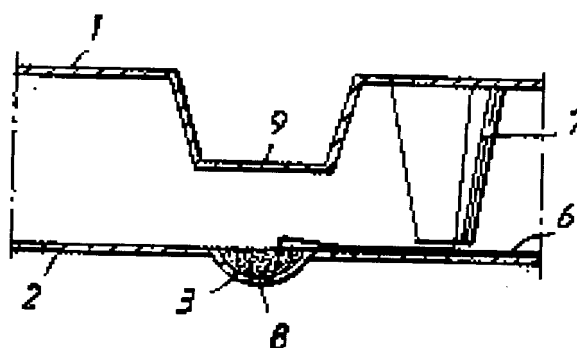
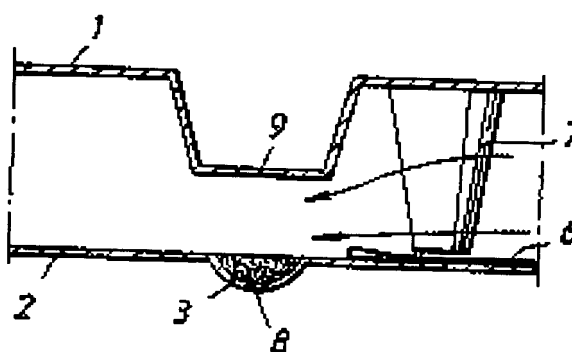


Fig. 3c



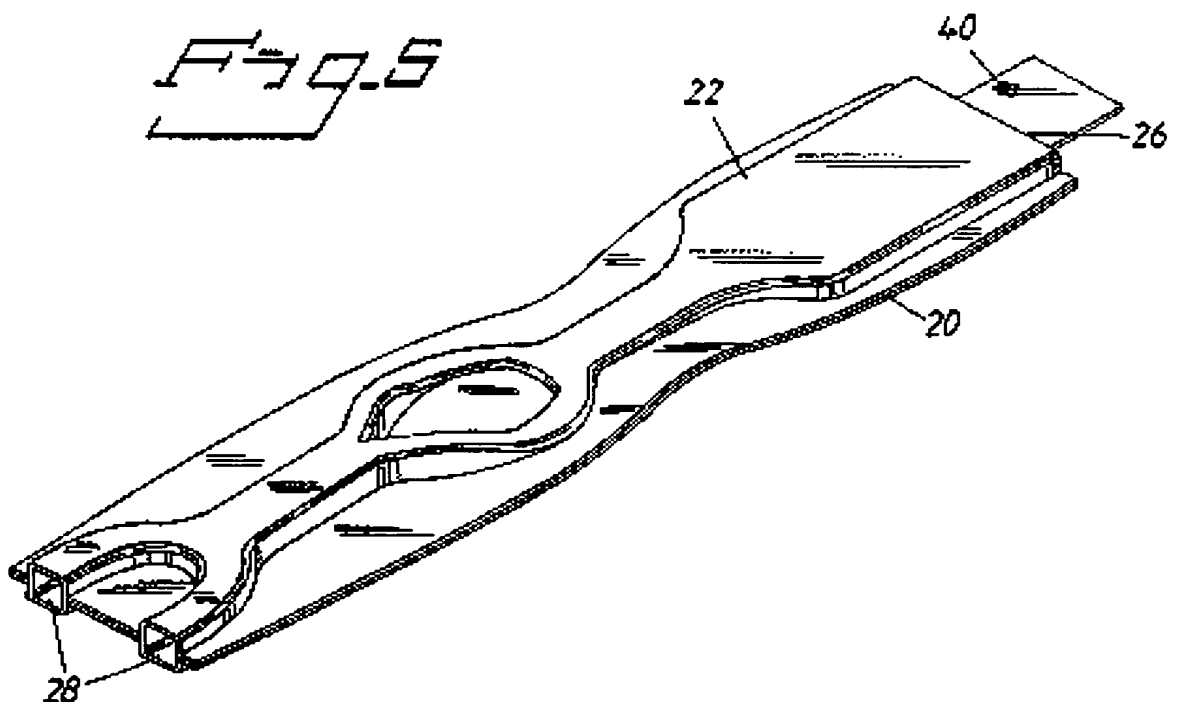


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Fig. 4



Fig. 5



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Fig. 6

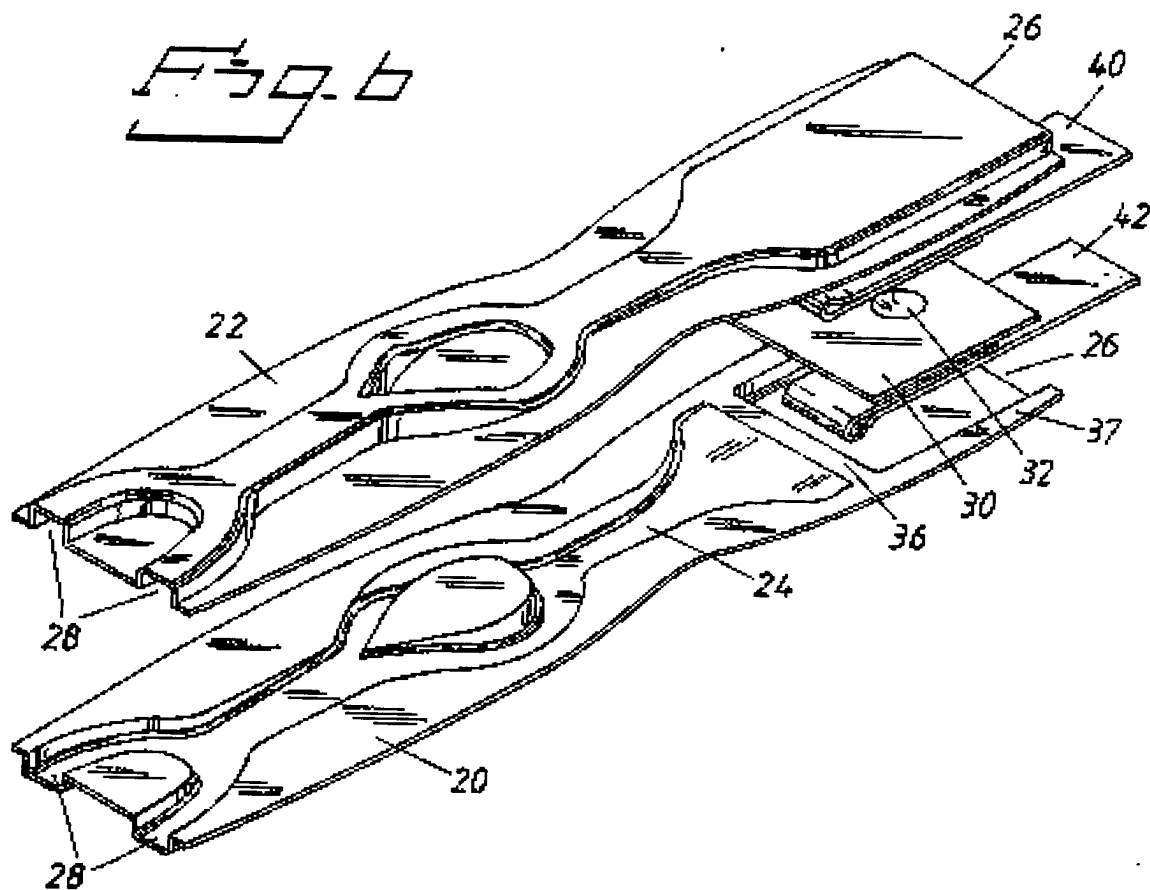
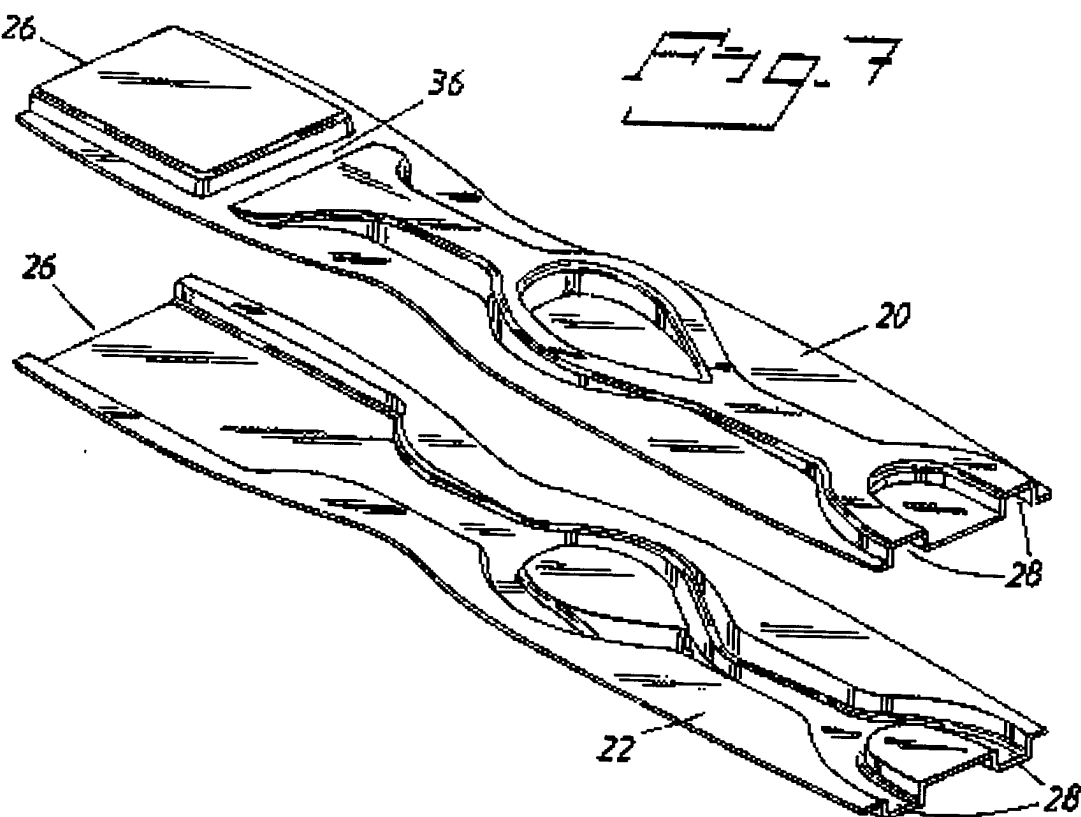


Fig. 7



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Fig. 8

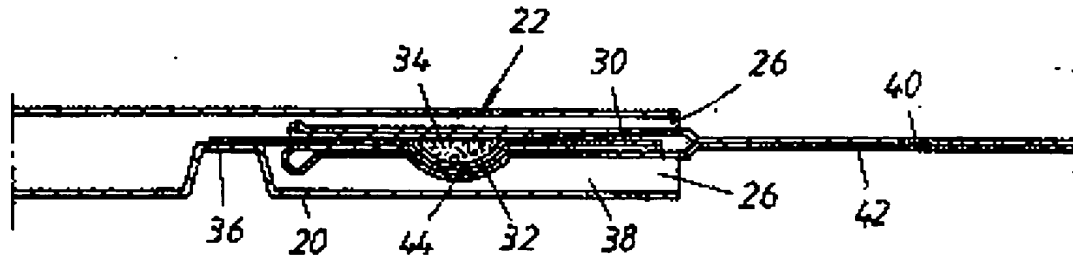


Fig. 9

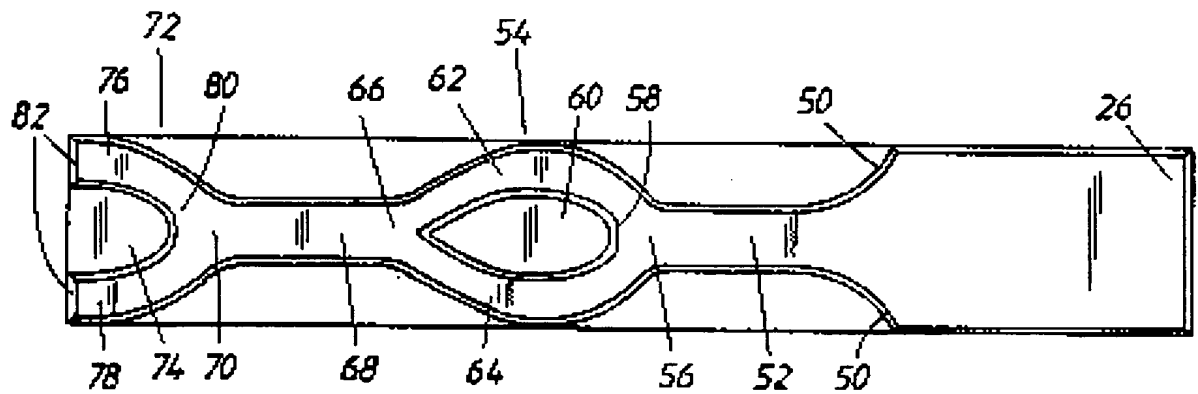


Fig. 10a

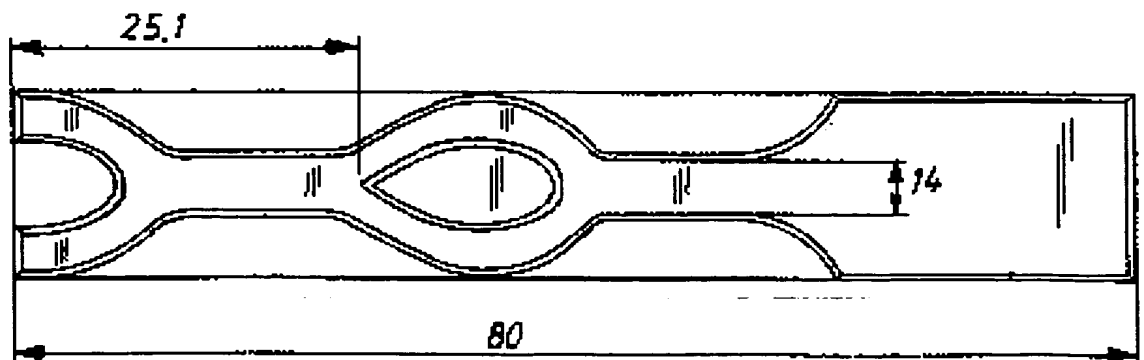


Fig. 10d

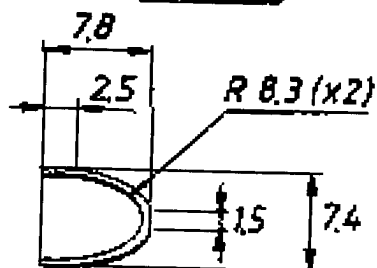


Fig. 10c

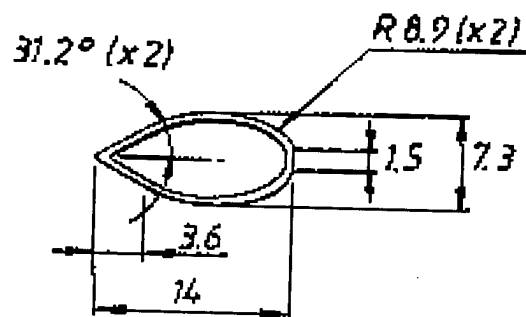


Fig. 10b

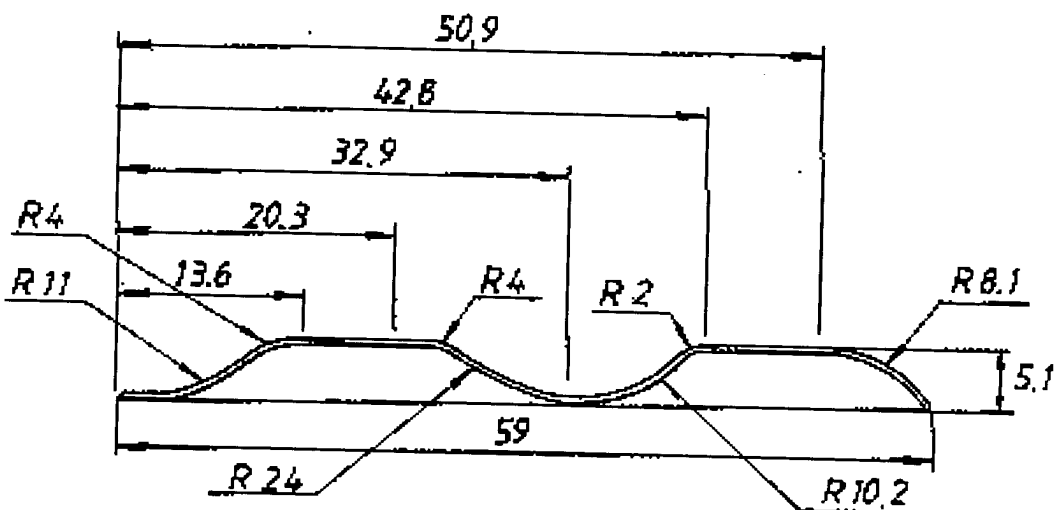


Fig. 11



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Fig. 12

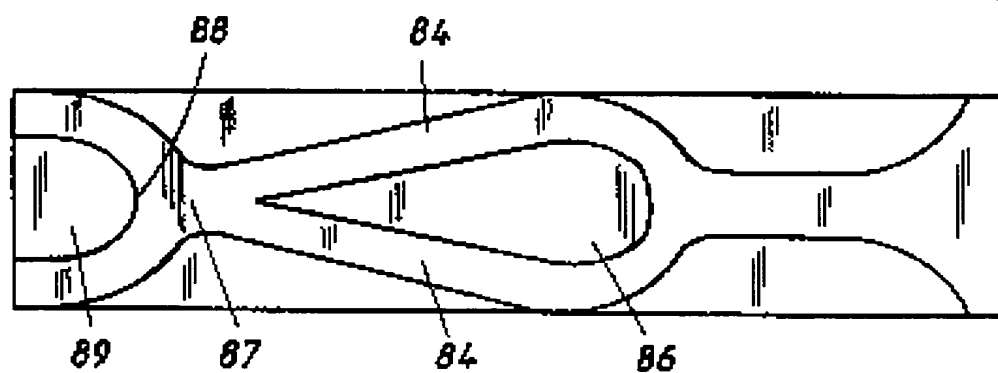


Fig. 13

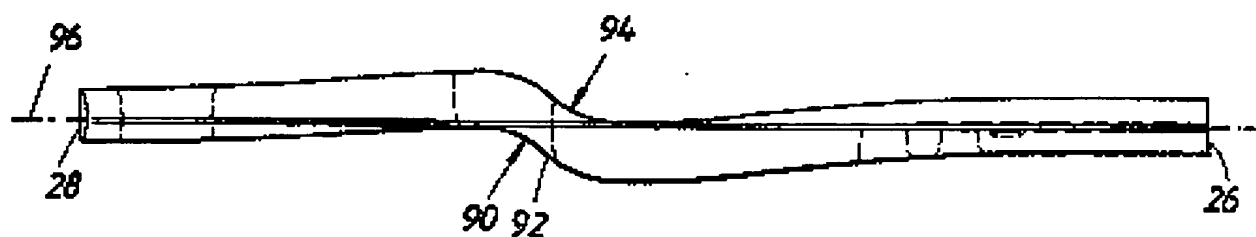
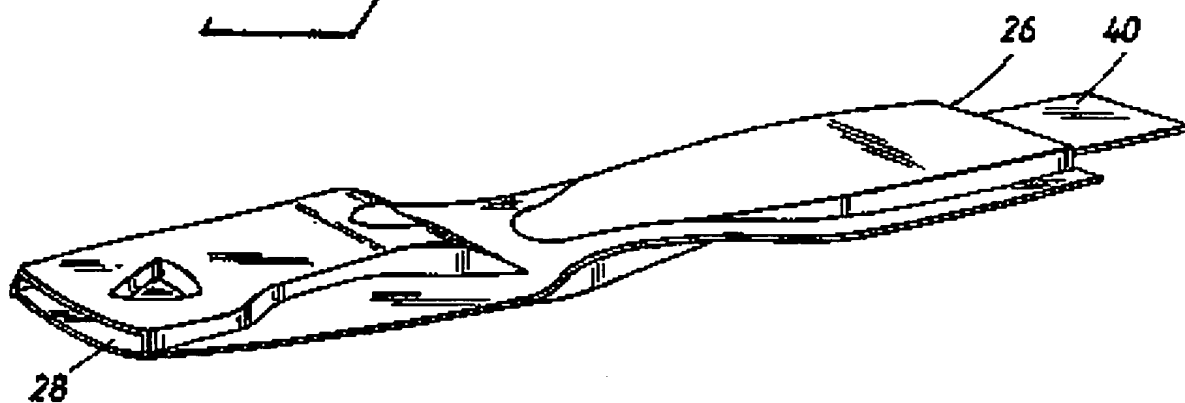


Fig. 14



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